Food and Drug Administration Rockville, MD 20857

July 28, 2004

Josephine M. Torrente Hyman, Phelps & McNamara, PC 700 Thirteenth Street, NW Suite 1200 Washington, DC 20005-5929

Dear Ms. Torrente:

Your petition requesting the Food and Drug Administration to require manufacturers of reprocessed single-use electrosurgical cutting and coagulation devices and accessories to submit validation data, was received by this office on 07/23/2004. It was assigned docket number 2004P-0334/CP 1 and it was filed on 07/23/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega, Deputy Director
Division of Dockets Management
Office of Management Programs

Office of Management